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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,947	08/27/2004	Yoshio Umezawa	2004_1136A	8461
513 7590 11/13/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER BURKHART, MICHAEL D	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 11/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,947

Applicant(s)

UMEZAWA ET AL.

Examiner

Michael Burkhardt

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9-14, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-14, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/24/2008 has been entered.

Receipt and entry of the amendment dated 6/24/2008 is acknowledged. After entry of the amendment, claims 1-5, 7, 9-14, 21 and 22 are pending and under examination.

Terminal Disclaimer and nonstatutory obviousness-type double patenting

The terminal disclaimer filed 6/24/2008 over U.S. patent 7,166,447 is acknowledged. However, the terminal disclaimer has not yet been reviewed or approved by USPTO paralegals. The Examiner has contacted such paralegals to request a prompt review and approval of the terminal disclaimer. Hence, the obviousness-type double patenting rejection of claims 1-5, 7, 9-14, 21 and 22 based upon the '447 patent is provisionally withdrawn, but will be reinstated if the terminal disclaimer is not approved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-14, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umezawa et al (WO 02/08766, 1/31/2002, of record) in view of Ozawa et al (Anal. Chem., 2001, of record), Hamilton et al (U.S. 6,780,599, of record), Simpson et al (EMBO reports, 2000, of record), and Martoglio et al (TICB, 1998, of record). **This rejection is maintained for reasons made of record in the Office Actions dated 5/15/2007, 2/25/2008, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 6/24/2008 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the organelle targeting peptide (OTS) of fusion peptide (a) and the test protein (b) of the instant invention do not directly interact, in contrast to the teachings of the prior art; 2) the interaction between fusion peptide (a) and fusion peptide (b) occurs in an indirect manner because the organelle lies between them; 3) protein splicing occurs when fusion proteins (a) and (b) are in close proximity at the surface of the target organelle.

Regarding 1), this is not a limitation of claims 5, 7, 9-14, 21, or 22. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., indirect interaction between the fusion proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants present no further arguments regarding these claims, hence, the rejections stands.

Further regarding 1), and regarding 3), amended claim 1 recites that the test protein does not directly interact with the OTS of the fusion peptide (a), not that the fusion peptides (a) and (b) themselves do not interact. The teachings of Umezawa, Ozawa, Hamilton, Simpson and Martoglio et al do not require or suggest such an interaction. A review of the previous Office Actions does not reveal the Examiner has ever suggested this to be a part of the logic or reasoning behind the rejection. Rather, it is the interaction between the intein half-peptides that is crucial to the methods of the prior art and of the instant invention. See for example, Figs. 1 and 2 of Ozawa et al and Fig. 1 of the instant invention. The OTS peptide is only required to direct fusion peptide (a) to the organelle of choice, there is no requirement or teachings of the OTS mediating the direct interaction of the fusion peptides (a) and (b). There are no teachings that the test protein must interact with the OTS of fusion peptide (a), rather it is suggested that the intein half-peptides will interact once they are localized to the same organelle. Furthermore, the structure of the components and method steps of the prior art are no different from those instantly claimed, and thus, any inherent properties of the claimed fusion peptides would also be found in the fusion peptides taught by the prior art. Finally, it is noted that the interaction of the

fusion peptides is not a step under control of applicants or the skilled artisan, it is a function of, and controlled by, the structure of the fusion peptides and the cells they are localized in. Thus, any teachings of the claimed fusion peptides would also be a teaching of any inherent properties these fusion peptides might have, e.g. the OTS not interacting with the test protein, or protein splicing occurring in close proximity.

Regarding 2) and 3), these arguments are false. A review of the instant specification and prior art reveals no evidence that the two fusion peptides can interact when separated by a membrane. Again, see Fig. 1 of the instant application, demonstrating that an interaction only occurs when the two fusion peptides are localized into the same organelle, i.e. they are not separated by an organelle membrane. Further, Fig. 1 indicates that protein splicing occurs inside the organelle, although it is conceivable that splicing would occur when both proteins are in proximity to the membrane, when on the same side of the membrane. Finally, a review of the application as filed does not reveal any instances wherein the fusion peptides (a) and (b), when separated by a membrane, resulted in a splicing event.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633